

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION**

IN RE MENTOR CORP. OBTAPE
TRANSOBTURATOR SLING
PRODUCTS LIABILITY LITIGATION

MDL CASE NO. 2004

Individual Case No. 4:11-cv-5065 (*Morey*)

**DEFENDANT MENTOR WORLDWIDE LLC'S ANSWER
AND AFFIRMATIVE DEFENSES**

Defendant Mentor Worldwide LLC ("Mentor") through its attorneys, hereby answers the First Amended Complaint ("Complaint") of Plaintiff Irene Morey ("Plaintiff") as follows:

JURISDICTION AND PARTIES

1. In response to Paragraph 1 of the Complaint, upon information and belief, Mentor admits the allegations contained therein.

2. In response to Paragraph 2 of the Complaint, Mentor denies that it is a Minnesota corporation. As of December 2009, Mentor is a limited liability company organized and existing under the laws of the State of Delaware. Mentor admits that its principal place of business is in California. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 2.

3. In response to Paragraph 3 of the Complaint, Mentor admits that Plaintiff is purporting to seek damages in excess of \$75,000. Except as specifically admitted, Mentor avers that the allegations contained in Paragraph 3 are legal conclusions that do not require an answer. To the extent that Mentor is required to answer, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 3.

4. In response to Paragraph 4 of the Complaint, Mentor admits that prior to December 2009, it was a Minnesota corporation. As of December 2009, Mentor is a limited

liability company organized and existing under the laws of the State of Delaware. Except as specifically admitted, Mentor avers that the allegations contained in Paragraph 4 are legal conclusions that do not require an answer. To the extent that Mentor is required to answer, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 4.

FACTUAL BACKGROUND

5. In response to Paragraph 5 of the Complaint, Mentor admits that, at certain times, it distributed ObTape Transobturator Tape (“ObTape”) to physicians and that ObTape was indicated for the surgical treatment of stress urinary incontinence. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 5.

6. In response to Paragraph 6 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

7. In response to Paragraph 7 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

8. In response to Paragraph 8 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

9. In response to Paragraph 9 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

10. In response to Paragraph 10 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

11. In response to Paragraph 11 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

12. In response to Paragraph 12 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

13. In response to Paragraph 13 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

14. In response to Paragraph 14 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

15. In response to Paragraph 15 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

16. In response to Paragraph 16 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

17. In response to Paragraph 17 of the Complaint, Mentor admits that it stopped marketing ObTape in or around March 2006. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 17.

18. In response to Paragraph 18 of the Complaint, Mentor admits that it stopped marketing ObTape in or around March 2006. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 18.

19. In response to Paragraph 19 of the Complaint, Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations stated therein and, on that basis, denies them.

20. In response to Paragraph 20 of the Complaint, Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations stated therein and, on that basis, denies them.

21. In response to Paragraph 21 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

COUNT I – NEGLIGENCE

22. In response to Paragraph 22 of the Complaint, Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1-21 of this Answer as if fully rewritten herein.

23. In response to Paragraph 23 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

24. In response to Paragraph 24 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

25. In response to Paragraph 25 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

26. In response to Paragraph 26 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

27. In response to Paragraph 27 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

COUNT II – PUNITIVE DAMAGES

28. In response to Paragraph 28 of the Complaint, Mentor incorporates by reference the admissions, denials, and averments of Paragraphs 1-27 of this Answer as if fully rewritten herein.

29. In response to Paragraph 29 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

30. In response to Plaintiff's "Prayer for Relief" and "Wherefore" clauses, Mentor denies that it is liable to Plaintiff for the requested relief or any relief whatsoever.

31. Mentor denies any allegation contained in the Complaint that is not expressly admitted by Mentor.

AFFIRMATIVE DEFENSES

Mentor maintains that discovery and investigation may reveal that one or more of the following affirmative defenses should be available to Mentor in this matter. Mentor, therefore, asserts said defenses to preserve the right to assert them as separate and distinct affirmative defenses to the Complaint and to the causes of action therein. Upon completion of discovery, and if the facts warrant, Mentor may withdraw any of its defenses as may be appropriate. Further, Mentor reserves the right to amend this Answer to assert additional claims or defenses as discovery proceeds.

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

(Statute of Limitations and Laches)

The claims against Mentor are barred, in whole or in part, by laches and/or the applicable statute of limitations.

THIRD AFFIRMATIVE DEFENSE

(Waiver and Estoppel)

The claims against Mentor are barred, in whole or in part, by waiver and/or estoppel.

FOURTH AFFIRMATIVE DEFENSE

(Modified Comparative Negligence)

If Plaintiff sustained damages by reason of the matters alleged in the Complaint, which is denied, then said damages were caused in whole or in part by Plaintiff's own negligence and fault and were not caused or contributed to in any manner, by any alleged fault, negligence or breach of warranty of Mentor, its officers, agents, contractors, servants, employees, or others for whom it was responsible. Plaintiff's recovery should be diminished by that percentage of fault

attributable to Plaintiff and/or persons or entities other than Mentor for those injuries sustained by Plaintiff upon which the damages complained of in this action are based. Thus, Mentor's liability, if any, is limited to its percentage of responsibility for the injuries of Plaintiffs, if any, regardless of whether or not other persons or entities are named as co-defendants. And to the extent that the percentage of fault attributable to Plaintiffs is greater than the percentage attributable to Mentor or others, Plaintiffs' recovery should be barred. Minn. Stat. § 604.01.

FIFTH AFFIRMATIVE DEFENSE

(Fault of Others)

If Plaintiff sustained damages as alleged in the Complaint, which is denied, said damages were caused solely by or contributed to by the acts and fault of third parties and were not caused or contributed to by any acts or fault of Mentor, its officers, agents, servants, employees, contractors, or others for whom it was responsible. Mentor will identify the other persons or entities that may have been responsible with as much particularity as is feasible as discovery progresses and in sufficient time to allow the Plaintiff to respond and/or file pleadings. Thus, Plaintiff's claims should be barred or proportionately reduced by the intentional and/or negligent acts of such known or unknown third parties.

SIXTH AFFIRMATIVE DEFENSE

(Mitigation of Damages)

If Plaintiff sustained damages as alleged in the Complaint, which is denied, Plaintiff has failed to mitigate her damages and any recovery is to be diminished by the degree to said failure to mitigate.

SEVENTH AFFIRMATIVE DEFENSE

(Assumption of Risk)

The allegations set forth in the Complaint are barred on the grounds that Plaintiff knew, or in the exercise of ordinary care should have known, of the risk of the injuries or damages

alleged in the Complaint, if any, and nevertheless did expressly, freely, and voluntarily assume said risk, and this undertaking proximately caused and contributed to the losses, injuries or damages, if any, alleged by Plaintiff.

EIGHTH AFFIRMATIVE DEFENSE

(Assumption of Risk/Informed Consent)

Upon information and belief, Plaintiff had full knowledge of the risks and possible adverse effects pertaining to the procedures performed upon her, and all or part of the alleged injuries, damages, and/or losses, if any, sustained by Plaintiff arose from and were caused by risks of which Plaintiff was aware, and such risks were accepted and assumed by her, and for that reason any recovery against Mentor should be diminished, reduced, offset, or barred in accordance with the principles of assumption of the risk and/or informed consent.

NINTH AFFIRMATIVE DEFENSE

(Collateral Sources)

Mentor is entitled to a set-off from any recovery against it to the extent each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, by collateral sources.

TENTH AFFIRMATIVE DEFENSE

(Superior Knowledge of Plaintiff's Physicians and Medical Care Providers)

At all times relevant hereto, the knowledge of Plaintiff's physicians and/or other medical care providers with respect to the possible risks of surgery and the opportunity to warn of the possible risks of surgery, was superior to that of Mentor, and, therefore, if there was any duty to warn Plaintiff of the risks of surgery, it was the duty of said physicians and/or other medical care providers, not of Mentor, and breach of that duty was an intervening and/or superseding cause of the injuries alleged by Plaintiff.

ELEVENTH AFFIRMATIVE DEFENSE

(Plaintiff's Physicians/Medical Care Providers Were Sophisticated Users)

Plaintiff's physicians and/or medical care providers, including their agents, servants and employees, by reason of the warnings and handling information given to them and their own long-standing and continuous experience with the products or materials, if any, referred to in the Complaint, are and were sophisticated users of any and all such products or materials, and thereby acquired a separate and affirmative duty to warn Plaintiff of any alleged potential harmful effects from the use or misuse of said products or materials. By reason of the foregoing, the failure of said physicians and/or medical care providers to discharge said duty directly and proximately caused any and all damages and injuries, if any, complained of by Plaintiff.

TWELFTH AFFIRMATIVE DEFENSE

(Learned Intermediary)

The device referred to in the Complaint is a medical device available only upon the prescription and/or order of a licensed physician and/or surgeon and is not available to the general public. Mentor provided information concerning warnings, precautions, and complications to those persons to whom the medical devices were available. Thus, Plaintiff's claims are barred, in whole or in part, by the "learned intermediary" doctrine. *Mozes v. Medtronic, Inc.*, 14 F.Supp.2d. 1124 (D. Minn. 1998).

THIRTEENTH AFFIRMATIVE DEFENSE

(Adequate Warnings)

If it is proven at the time of trial that Plaintiff came into contact with Mentor's product, which is denied, then any product manufactured and/or sold and/or distributed by Mentor which was or may have been furnished to Plaintiff and which she came into contact or may have come into contact with, was furnished with adequate and appropriate warnings.

FOURTEENTH AFFIRMATIVE DEFENSE

(Alteration of Products)

Plaintiff's physicians and/or medical care providers may have modified, altered or changed the Mentor products, if any, referred to in the Complaint, so that such changes in any said products or materials proximately caused Plaintiff's injuries, loss and damages, if any.

FIFTEENTH AFFIRMATIVE DEFENSE

(Benefits Outweigh Risks)

The benefits of Mentor products or materials, if any, referred to in the Complaint outweigh the risk of danger and/or harm, if any, inherent in said products or materials.

SIXTEENTH AFFIRMATIVE DEFENSE

(No Representation to the Public)

With respect to the medical device referred to in the Complaint, if any were manufactured by Mentor, no representations were made by Mentor to the public at large in order to induce purchase of said products or materials.

SEVENTEENTH AFFIRMATIVE DEFENSE

(Independent, Intervening, or Superseding Cause)

Plaintiff's injuries, if any, were proximately caused by unforeseeable, independent, intervening and/or superseding event(s) beyond the control, and unrelated to any conduct, of Mentor. Mentor's actions or omissions, if any, were superseded by the negligence and wrongful conduct of others.

EIGHTEENTH AFFIRMATIVE DEFENSE

(Alternate Cause)

The injuries and damages of which Plaintiff complains were not caused by any product distributed by Mentor, but were caused by some other product, process, occurrence, event or service over which Mentor exercised no control or right of control.

NINETEENTH AFFIRMATIVE DEFENSE

(Preemption of Federal Law)

Federal statutes and regulations preempt all state law governing the product that is the subject of the Complaint, and said product was in compliance with federal law at all times relevant to this cause of action.

TWENTIETH AFFIRMATIVE DEFENSE

(Restatement (Second) of Torts)

The claims against Mentor are barred, in whole or in part, by the provisions of Comments “j” and “k” to Section 402 of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

(State of the Art)

Any and all acts performed by, and products designed and manufactured and/or distributed by Mentor were at all times relevant to the Complaint in conformity with the state of the art for the design and manufacture of such similar devices, and thus Plaintiff’s claims are barred.

TWENTY-SECOND AFFIRMATIVE DEFENSE

(State of the Art)

The actions of Mentor were in compliance with all existing safety standards and precautions then consistent with the state of the medical art, and thus, Plaintiff’s claims are barred.

TWENTY-THIRD AFFIRMATIVE DEFENSE

(Open and Obvious)

Any dangers associated with the use of the medical devices that may have caused Plaintiff’s injuries, if any, were open and obvious, and Plaintiff is therefore barred from recovery.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

(Idiosyncratic Reaction)

Some or all of the injuries alleged in the Complaint were caused or aggravated by Plaintiff's pre-existing medical condition or exposure to other substances utilized throughout her lifetime, by Plaintiff's unusual susceptibility to injury, or by her idiosyncratic reaction.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

(Conformity with Governmental Regulations)

Any and all warnings or information pertaining to products designed, manufactured and/or distributed and/or sold by Mentor were at all times relevant to the Complaint in conformity with governmental requirements.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

(Conformity with Governmental Standards)

The formula, labeling, and/or design of any products designed, manufactured and/or distributed and/or sold by Mentor at all times relevant to the Complaint complied with mandatory safety standards or regulations adopted and promulgated by the federal government or an agency of the federal government, entitling Mentor to a rebuttable presumption that Mentor is not liable for any harm to Plaintiff as claimed in the Complaint.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

(UCC Defenses)

Mentor is entitled to the benefits of all defenses and presumptions contained in, or arising from, any Uniform Commercial Code provisions enacted by the State of Minnesota or the state of Plaintiff's residency.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

(Unintended and Unforeseeable Misuse, Modification, or Abuse of the Product)

If any product manufactured, distributed or sold by Mentor caused harm as alleged, which is denied, then such harm was proximately caused by misuse, modification, and/or abuse of the product in a manner neither intended nor foreseen by Mentor.

TWENTY-NINTH AFFIRMATIVE DEFENSE

(No Feasible Alternative Design)

Mentor states that there is no alternative design for the product that was capable of preventing Plaintiff's injuries.

THIRTIETH AFFIRMATIVE DEFENSE

(Preemption)

The conduct of Mentor and all activities with respect to the subject product have been and are under the supervision of the United States Food and Drug Administration. Accordingly, this action is barred by the doctrine of primary jurisdiction and preemption.

THIRTY-FIRST AFFIRMATIVE DEFENSE

(Accord and Satisfaction/Release)

Plaintiff's claims are barred by the doctrine of accord and satisfaction and/or release.

THIRTY-SECOND AFFIRMATIVE DEFENSE

(Restatement (Third) of Torts)

The claims against Mentor are barred, in whole or in part, by the provisions of Section 6(c) of the Restatement (Third) of Torts.

THIRTY-THIRD AFFIRMATIVE DEFENSE

(Improper Pleading)

To the extent that Plaintiff's Complaint purports to state claims for fraud and/or misrepresentation, the Complaint fails to comply with the requirements of Rule 9(b) of the Federal Rules of Civil Procedure and should be dismissed.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

(Damages Unrecoverable)

All or some of Plaintiff's claims for damages have not accrued and are too speculative, uncertain, and contingent to be recoverable.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

(Punitive Damages Unconstitutional)

Plaintiff's claims for punitive damages are in contravention of Mentor's rights under each of the following constitutional provisions:

- a. the Commerce Clause of Article I, Section 8 of the United States Constitution;
- b. the Contracts Clause of Article I, Section 10 of the United States Constitution;
- c. the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution;
- d. the Supremacy Clause of Article VI of the United States Constitution;
- e. the Free Speech Clause of the First Amendment of the United States Constitution;
- f. the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;
- g. the Takings Clause of the Fifth Amendment of the United States Constitution
- h. the Right to Counsel of the Sixth Amendment of the United States Constitution;

- i. the Excessive Fines Clause of the Eighth Amendment of the United States Constitution;
- j. the Right to Trial by Jury contained in the Seventh Amendment of the United States Constitution;
- k. the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and
- l. similar or corresponding provisions of the Constitution of the State of Minnesota or the state of Plaintiff's residency.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

(Punitive Damages Barred)

No act or omission of Mentor was fraudulent, malicious, oppressive, or grossly negligent and, therefore, any award of punitive damages is barred.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

(Punitive Damages Barred)

With respect to Plaintiff's demand for punitive damages, Mentor specifically incorporates by reference any and all standards, caps or limitations regarding the determination and enforceability of punitive damage awards that are set forth in *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and similar State cases and statutes.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

(Punitive Damages Barred)

Because of the lack of clear standards, any imposition of punitive damages against Mentor would be unconstitutionally vague and/or overbroad.

THIRTY-NINTH AFFIRMATIVE DEFENSE

(Punitive Damages Improperly Pled)

Plaintiff's demand for punitive damages is improperly pled and should be dismissed.

Minn. Stat. § 549.191.

FORTIETH AFFIRMATIVE DEFENSE

(Notice of Additional Affirmative Defenses)

Mentor hereby gives notice that it intends to rely upon such other affirmative defenses as may become available or apparent during the course of discovery and thus reserves the right to amend its Answer to assert such defenses.

WHEREFORE, Defendant Mentor Worldwide LLC prays as follows:

1. That Plaintiff take nothing by virtue of the Complaint herein and that this action be dismissed in its entirety;
2. For costs of suit and attorneys' fees herein incurred; and
3. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Defendant Mentor Worldwide LLC demands a jury trial of all issues so triable.

Dated: January 30, 2013

Respectfully submitted,

s/ John Q. Lewis

John Q. Lewis

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*Designated Lead Counsel for Defendant
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**IN RE: MENTOR CORP. OBTAPE TRANSOBTURATOR
SLING PRODUCTS LIABILITY LITIGATION**

MDL NO. 2004

CERTIFICATE OF SERVICE

A copy of the foregoing filing was served via ECF and by electronic mail on the following counsel this 30th day of January 2013:

Matthew N. Metz, Esq.
matthew@metzlaw.net
Attorney for Plaintiff

s/ John Q. Lewis
Attorney for Defendant
Mentor Worldwide LLC